UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,753	12/21/2001	Ronald G. Udell	SGTI-40565	3723

7590 08/12/2002

Kamran Fattahi, Esq.
Kelly Bauersfeld Lowry & Kelley, LLP
Suite 1650
6320 Canoga Avenue
Woodland Hills, CA 91367

EXAMINER	
MCINTOSH III, TRAVISS C	
ART UNIT	**PAPER NUMBER**
1621	2

DATE MAILED: 08/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)	
	10/035,753	UDELL ET AL.	
	Examiner	Art Unit	
	Traviss C McIntosh	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Detailed Action

Claims 1-15 are pending in the instant application.

Claim Objections

Claims 2, 6-10, 14, and 15 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 6-9 recite an intended use of the claimed composition and thereby do not further limit the composition as claimed. Applicant's source for hyaluronic acid as recited in dependent claims 2, 10, 14, and 15 is of no patentable import and therefore these claims do not further limit the claims they depend from.

Applicant is advised that should claim 1 be found allowable, claims 2 and 6-10 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. Additionally, applicant is advised that should claim 11 be found allowable, claims 14 and 15 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 11 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as the term "low molecular weight" is a relative term which renders the claim indefinite. The term "low molecular weight" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Additionally, claims 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant's recitation in claim 11 of a method of "internally softening the human skin" is indefinite as it is unclear as what is meant to be encompassed by the instant invention. Is the skin (epidermis and dermis) being softened from a composition which is within the body, or is the skin on the interior of the body (dermis) being softened? Further, the examiner is unclear as to what is meant to be encompassed by recitation of the term "softening", is the skin softer to the touch thereby becoming smoother, or is it being reduced in strength, yielding readily to pressure or weight and becoming more flexible or more easily penetrated?

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, and 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Falk et al. (US Patent 5,811,410). Claim 1 of the instant application is drawn to a orally administered

composition comprising 35-45 mg of a hyaluronic acid having a molecular weight of between 50,000-200,000 daltons.

Falk et al. disclose a composition comprising 5-80 mg of hyaluronic acid (column 5, lines 6-7) having a molecular weight from 50,000 daltons upwards (column 4, lines 32-37), preferably in the range of 150,000-225,000 daltons (column 17, lines 32-44) wherein the formulation can be administered orally (column 10, lines 37-40).

Further, the process limitations of making or using the composition as set forth in the depending claims 2 and 6-10 of the instant application cannot impart patentability to the composition which is not patentably distinguished over the prior art, and thus these claims are anticipated by the prior art of Falk et al. ***In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).***

The disclosure of the composition of Falk et al. is seen to anticipate the composition as set forth in claims 1, 2, and 6-10 of the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al. as applied to claims 1, 2, and 6-10 above, and further in view of Yano et al. (US Patent 4,443,459).

The claims of the instant application are drawn to a hyaluronic acid composition as noted above and which is incorporated herein as reference, and additionally including beeswax and rice bran oil and wherein the composition is formulated into a soft gelatin capsule.

Falk et al. disclose the hyaluronic composition as noted above and which is incorporated herein as reference. What Falk et al. do not disclose is to add beeswax or rice bran oil to the composition nor to formulate the composition into a soft gelatin capsule.

Yano et al. teach of a pharmaceutical composition comprising an active ingredient and diluents or carriers wherein the diluents or carriers can be beeswax and rice bran oil. Yano et al. additionally teach that the composition may be in various forms such as soft capsules, hard capsules, granules, and tablets (column 4, line 60 – column 5, line 5). What Yano et al. do not teach is to use hyaluronic acid as the active ingredient in the composition.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of the Falk et al. and Yano et al. wherein the specified hyaluronic acid of Falk et al. is the active ingredient in the composition of Yano et al. because the limitations as taught by Yano et al. are disclosed as being known in the art of pharmaceutical compositions as common forms of diluents and carriers. One would be motivated to incorporate the hyaluronic acid of Falk et al. into the beeswax and rice bran oil soft gelatin

capsule of Yano et al. as to form an oral composition of hyaluronic acid whereby one would avoid the use of topical cosmetics, which frequently contain scents and additives not always pleasing to consumers, and injections, which cause pain and discomfort for the majority of consumers, as the main form of administration.

Claims 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falk et al. and Yano et al. as applied to claims 3-5 above, and further in view of Nigra et al. (US Patent 6,028,105).

The claims of the instant invention are drawn to a method of internally softening the skin comprising orally administering a composition of a hyaluronic acid which has a molecular weight of between 50,000 and 200,000 daltons wherein the dosage of the hyaluronic acid is between 35-45 mg. Please note that because the specification does not define the meaning of "internally softening the human skin" it is being interpreted as meaning softening the skin to a smoothness thereby eliminating any roughness of the skin wherein the functional agent (hyaluronic acid) is functioning internally, rather than as a topical treatment (cream or spray) functioning on the exterior of the skin.

Falk et al. and Yano et al. teach of the hyaluronic composition as noted above and which is incorporated herein as reference. What they do not teach is the method of using this composition as a means of softening the human skin.

Nigra et al. teach that hyaluronic acid is suitable for use as a skin softening agent (column 4, lines 26-30) wherein Nigra et al. teach that the skin becomes softened and smoothed rather than suffer from other prior art delivery vehicles such as dry, cracked, red, irritated skin (column 2, lines 45-50). What is not taught by Nigra et al. is the use of the composition as one which is

orally administered and wherein the dosage is between 35-45 mg and the molecular weight is in the range of 50,000 – 200,000 daltons.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the oral composition as taught by Falk et al. and Yano et al. as a method of internally softening the skin because Nigra et al. teach that hyaluronic acid is used as an agent to soften the skin. The motivation to use the hyaluronic acid composition as an oral means of softening the skin is that an oral form of a composition would allow one to avoid the use of topical cosmetics, which frequently contain scents and additives not always pleasing to consumers, and injections, which cause pain and discomfort for the majority of consumers.

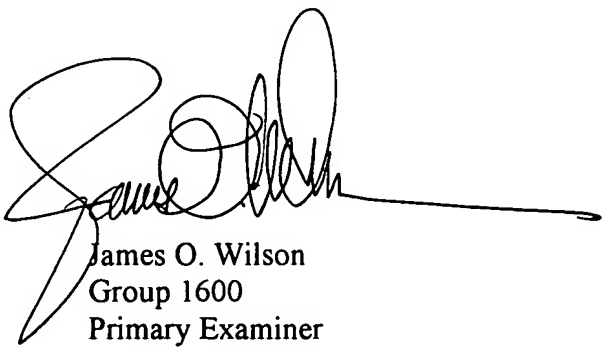
Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C. McIntosh whose telephone number is 703-308-9479. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



James O. Wilson
Group 1600
Primary Examiner

Traviss C. McIntosh
August 8, 2002